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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,588	01/21/2004	Grigoriy S. Tchaga	CLON-056US2	3721

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,588

Applicant(s)

TCHAGA ET AL.

Examiner

Agnes B Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This final action is in response to the Applicant's reply filed on May 12, 2005.

Claims 11-13 and 16-22 are pending. Claims 1-10 are cancelled, and claims 18-22 are new.

This application is a CIP of 09/858,332, filed on 05/15/2001, and claims benefit of 60/441,804, filed on 01/21/2003.

All rejections and objections not mentioned in this office action are withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 102

Rejection of Claims 1-13 and 16-17 is maintained.

In the previous office action examiner stated that Claims 11-13 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Porath et al., "Immobilized Metal Ion Affinity Adsorption and Immobilized Metal Ion Affinity Chromatography of Biomaterials. Serum Protein Affinities for Gel-Immobilized Iron and Nickel Ions," Biochemistry (1983), 22, p. 1621-1630.

Porath et al. teach metal chelate affinity chromatography for purification of serum proteins, where gels are loaded with the same or different metal ion, for example Ni(II) and Fe(III) (Claims 11-13, and 17). See *Abstract*.

Porath et al. prepared different columns, for example "IDA-Sepharose 6B" or "TED-Sepharose 4 B" with bound Ni(II) or bound Fe(III), where each chelator gel was packed

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in a separate column (Claims 11-13, and 17). See page 1622 (*Materials and Methods* section). Different combinations of columns were formed, where two or more columns were packed with one type of chelator gel (e.g., TED-Sepharose) and loaded with different metal ions (e.g., Ni(II) or Fe(III)) to form "tandem columns" (Claims 11-13, and 17). See page 1622 (*Chromatography* section). Different combinations of "tandem columns" were created where Fe(III)-TED bed proceeded Ni(II)-TED or Ni(II)-TED bed preceded Fe(III)-TED bed (Claims 11-13, and 17) See page 1624 (*Results* section). The following buffers were used for extraction, wash, and elution purposes: 0.05M sodium acetate and 0.1 M NaCl, pH 5.5; 0.1 M Tris-HCl, pH 8.1; 0.5 M sodium acetate, pH 5.5; and 1M glycine, pH 9.0 (Claims 11 and 16).

Therefore, Claims 11-13, 16 and 17 of the instant invention are anticipated by Porath et al. since all limitations of the claims are addressed.

Applicant responded that Porath et al. discloses differential affinity of serum protein to gel-immobilized iron or gel immobilized nickel ions. Porath et al. fails to disclose in a single kit for purifying a protein comprising a first composition and a second composition as claimed in the present application.

Examiner respectfully disagrees because a column made up of two compositions could be considered a kit for purpose of protein purification.

Therefore, the rejection is maintained.

New Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porath et al. in view of Nelson et al. (U.S. 5,962,641).

The teachings of Porath et al. are disclosed above, where they do not teach Co(2+) as a transition metal in a matrix in the column.

Nelson et al. teach a method of purification of recombinant proteins, where Co(2+) is used in the matrix. See column 2, line 41 or Claim 2.

It would have been obvious to one skilled in the art to modify teachings of Porath et al. by adding Co(2+) to a resin for the purification of proteins, since as suggested by Nelson et al. Co(2+) can be used in the matrix for protein purification purposes.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

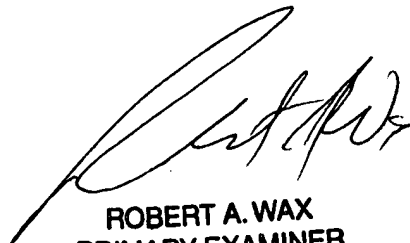
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-273-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have

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questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR



ROBERT A. WAX
PRIMARY EXAMINER